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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,297	04/19/2001	Wang-Shick Ryu	0257-0003	9633

7590 10/02/2003
TransPotomac Plaza
Suite 306
1033 N. Fairfax St.
Alexandria, VA 22314

EXAMINER

FOLEY, SHANON A

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/837,297

Applicant(s)

RYU ET AL.

Examiner

Shanon Foley

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10, drawn to a recombinant Hepatitis B virus vector, classified in class 435, subclass 320.1.
 - II. Claim 11, drawn to a helper plasmid, classified in class 536, subclass 23.1.
 - III. Claims 12-13, drawn to a method for making a recombinant HBV particles vector, classified in class 435, subclass 69.1.
 - IV. Claims 14-16, drawn to a method for transducing target cells with HBV particles, classified in class 435, subclass 70.1.
 - V. Claims 17-19, drawn to a method for transducing target cells with HBV vector DNA, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

a) Inventions I and (II and IV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a viral vector and a helper plasmid. There is no disclosed relationship between the two products regarding their use together. They have different modes of operation, function and effect. Further, the products and method (transducing target cells with HBV particles) are not disclosed as capable of use together.

b) Inventions I and (III and V) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case product can be used in a materially different process such as making recombinant HBV particles, transducing target cells with HBV vector DNA, or inducing an immune response.

c) Inventions II and (III-V) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the product, helper plasmid, is not disclosed as capable of use with any of the methods of inventions III-V. They have different modes of operation, function and effect.

d) Inventions III-V are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods that result in different outcomes, operate by different functions and have different effects. The methods are not disclosed as capable of use together.

Because these inventions are distinct for the reasons given above and the literature search required for one group is not required or not co-extensive for any other group, and therefore burdensome, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is 703-308-3983. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read "Shanon Foley". The signature is written in a cursive, flowing style with a large initial "S".

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

EXAMINER'S CASE ACTION WORKSHEET

Application No. 09/837,297		Legal Instrument Examiner
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CHECK TYPE OF ACTION

DATE OF COUNT

<input type="checkbox"/> Non-Final Rejection	<input checked="" type="checkbox"/> Restriction/Election Only	<input type="checkbox"/> Final Rejection
<input type="checkbox"/> Ex Parte Quayle	<input type="checkbox"/> Allowance	<input type="checkbox"/> Advisory Action
<input type="checkbox"/> Examiner's Answer	<input type="checkbox"/> Reply Brief Noted	<input type="checkbox"/> Non-Entry of Reply Brief
<input type="checkbox"/> Defective Notice of Appeal	<input type="checkbox"/> Interference Disposal SPE _____ (Approval for Disposal)	<input type="checkbox"/> Suspension (Examiner-Initiated) SPE _____ (initial)
<input type="checkbox"/> Defective Appeal Brief	<input type="checkbox"/> SIR Disposal (use only after FAOM)	<input type="checkbox"/> Supplemental Examiner's Amendment
<input type="checkbox"/> Miscellaneous Office Letter (With Shortened Statutory Period Set)	<input type="checkbox"/> Notice of Non-Responsive Amendment (With One Month Time Period set)	<input type="checkbox"/> Miscellaneous Office Letter (No Response Period Set)
<input type="checkbox"/> Abandonment after BPAI Decision	<input type="checkbox"/> Supplemental Action (excluding Examiner's Answer)	<input type="checkbox"/> Response to Rule 312 Amendment
<input type="checkbox"/> Letter Restarting Period for Response (e.g., Missing References)	<input type="checkbox"/> Interview Summary	<input type="checkbox"/> Authorization to Change Previous Office Action SPE: _____ (Initial)
<input type="checkbox"/> Abandonment	<input type="checkbox"/> Express Abandonment Date: _____	<input type="checkbox"/> Other Specify: _____

Examiner's Name: Shanon Foley

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